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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/929,596

08/13/2001

Todd K. Whitehurst

AB-125U

9185

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7590

05/06/2004

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EXAMINER

MACHUGA, JOSEPH S

ART UNIT

PAPER NUMBER

3762

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DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,596

Applicant(s)

WHITEHURST ET AL.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-21 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,14-21 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-11, 14-19 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho #4703755 in view of Gross et al #6354991 and Schulman #5193540.

4. Tanagho et al discloses a method and device for controlling organs such as the bladder, bowel, colon and associated sphincters and cuffs. The system stimulates the S2, S3, S4 sacral nerves. Power and stimulation parameters are provided from an external component. Not disclosed by this reference is the step of providing an inhibiting pulse to the sacral nerve to control incontinence through an internally placed stimulator.

5. Gross et al teach in column 2 lines 29-44 that it is old and well known to provide continuous electrical stimulation of the sacral nerve to reduce or eliminate urge incontinence. The reference also teaches adding a sensor to the bladder to detect increases in the bladder pressure and provide appropriate feedback to a controller.

6. Schulman et al discloses an implantable micro stimulator having electrodes, rechargeable power supply and a control circuit integrated into a single compact implantable unit. Control instructions/parameters and batteries recharging is provided by an external interface. This arrangement provides a device that can be easily implanted into a patient through a hypodermic needle. The reference also teaches that multiple micro-stimulators can be used.

It would have been obvious to one of ordinary skill in the art to apply make Tanagho et al's device as a self contained implant having a rechargeable battery and control circuits given Shulman et al's disclosure that this design is old and well known and provides the benefit of providing an implant that is simpler to place in the patient. To apply a continuous electrical stimulation of the sacral nerve or adjacent nerve bundles for the purpose of reducing or eliminating urge incontinence would have been obvious to one of ordinary skill in the art given Gross et al's teaching that this is known to reduce or eliminate urge incontinence. To add a sensor to the bladder to detect changes in its pressure and transmit that information to the controller of the proposed combination to provide accurate information about the contents of the bladder would also have been obvious given Gross et al's teaching of this.

These obvious modification would provide the method steps of providing operating power and providing stimulating parameters to the stimulator and generating inhibitory stimulation pulses as required by the claims. To use multiple micro-stimulators to add

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control over other adjacent nerves such as the S2, S4, pelvic splanchnic nerves, rectal nerve plexuses (nerves also known to also influence urinary and fecal incontinence) would also have been obvious given Shulman et al's disclosure.

7. Claims 20, 21, 25-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho #4703755 in view of Gross et al #6354991 and Schulman #5193540 as applied to claims 1, 3-11, 14-19 and 31 above, and further in view of Lin #5833595.

Lin discloses a device for controlling bladder function. The reference teaches stimulating the nerves of the L1 to S5 vertebrae to control bladder function. Given Lin's teaching it would have been obvious to one of ordinary skill in the art to provide inhibitory stimulation pulses to control the nerves of the L1 or L2 vertebrae to control bladder function in patients.


Response to Amendment

8. Applicant's arguments with respect to claims 1, 3-11, 14-21, 25-32 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph S. Machuga
Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700